REMARKS

In response to the above referenced Office Action, Applicant respectfully asserts that the claims are patentably distinguishable over the references of record and the restriction requirement is improper and unsupportable. Accordingly, Applicant respectfully requests withdrawal of the rejection and examination and consideration of the restricted claims.

With reference to claim 37, as an example, the claimed subject matter is directed to an ostomy appliance that includes a central ring having two different adhesives; a moisture absorbing adhesive on a skin contacting side and a hydrophobic adhesive on the opposite side. When the ring is rolled to form a torus, the two adhesive layers, which are selected to cooperate with one another adhere and hold or lock the torus in the rolled shape/configuration selected by the user.

Nielsen is completely devoid of *any* such teaching. In every embodiment, the adhesive mass 7 is configured so as to have an upper surface that is non-tacky and there is no teaching to provide an exposed or exposable adhesive layer on this upper surface. Further, there is no teaching to roll the edge to form a torus and "lock" the torus into the rolled configuration. Assertions to the contrary are simply unsupported by the factual record.

The Examiner has focused on one ambiguous line of text in the Nielsen reference and interpreted this line in a manner that is clearly inconsistent and opposed to the remainder of the reference. Specifically, at page 8, lines 13 – 14, the reference states that the "mouldable backing stretches out beyond the outer periphery of the ring in the form of a flange or adhesive layer. "

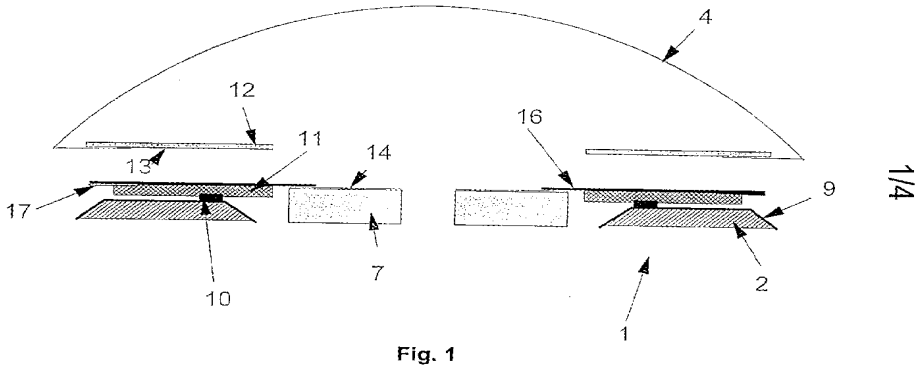

Fig. 1

Figure 1 of the reference is reproduced above. Element 7 is the adhesive mass. The mouldable backing 14 is disposed across the upper surface of the adhesive mass 7. A separate sealing member 16 is provided as part of or in combination with the adhesive mass 7 so as to connect (via adhesion) the sheet 16 to the flange 11. The sheet 16 then serves as the interface to which the adhesive layer of the bag 4 adheres (coupling the bag 4 to the flange 11).

No less than five (5) separate times in the specification, the references states unambiguously that the mouldable backing protects the adhesive mass 7 and "prevent[s] a tacky surface on the side facing the bag."

The "flange or adhesive layer" referred to on page 8 is a reference to the surface that covers the flange 11 of the body side member to effectively become the flange surface to which the bag 4 is adhered (adhesive layer). That flange 11 bonds to sheet 16, sheet 16 bonds to bag 4 via adhesive layer 13.

Whatever the adhesive characteristics of the adhesive mass 7 are, they are consistent throughout. The mouldable backing is a protective member; not a release liner selectively covering adhesive and if removed, the exposed surface of the mass 7 would be the same adhesive material provided on the skin facing surface.

Accordingly, Nielsen fails to teach a wafer having two different adhesives that when placed together bond to hold the selected shape.

In the Office Action, the Examiner has made a number of statements that are not supported by the written record. At paragraph 2, the Examiner states that Nielsen suggests a

central part of the second surface (mouldable backing) is provided with a hydrophobic adhesive layer. The claims require a wafer having two different adhesives on opposite surfaces that are brought into contact with one another. The upper surface of the mouldable backing in the reference is *explicitly devoid* of adhesive so as to prevent a "tacky surface." While Applicant does not concede such a teaching is present, to the extent adhesive is used to secure the mouldable backing to the adhesive mass, this fails to teach the elements of the claims since this adhesive would not contact that of the skin contacting surface. Thus, the Examiner's detailed postulation regarding the purported hydrophobic nature of this phantom adhesive is speculative at best; certainly unsupportable, and would not teach the claimed invention even if permissible.

The Examiner next states that Nielsen discloses "that the torus is held in its locked position by swelling of the hydrocolloid adhesive." This statement is inaccurate on both points. Nowhere in the reference does Nielsen teach "locking" the torus *in any manner*. If fact, immediately upon release by the person rolling the adhesive mass, that mass is free and begins to return to its original form. There are no adhesive layers cooperating to hold the mass in the rolled position and it is not the intent of Nielsen to do so. Further, the "swelling" does not hold the torus in the rolled shape; it does the *exact opposite* by helping return the adhesive mass to its original form.

The language the Examiner cited reads:

> The enlargement of the hole of sealing member is preferably carried out by everting and rolling the inner ring forming a torus which *after release will unroll and seal against the stoma* . . . [t]he release may be effected . . . *by influence of humidity causing a hydrocolloid-containing adhesive to swell.* (Emphasis Added)

With respect to the restriction requirement, the Examiner inappropriately characterizes the hydrophobic adhesive layer as being defined by a carrier sheet and that this combination forms an essential element. Such an interpretation is not required by the claims. For example, claim 37 defines a wafer with 2 different adhesives on opposite surfaces and includes a carrier sheet. In dependent claim 40 "the carrier sheet is absent on said central part of the second surface of said wafer surrounding the stoma and having said hydrophobic adhesive layer thereon." Dependent claim 41 recites that the hydrophobic adhesive layer stretches under the carrier sheet. The carrier sheet does not form the hydrophobic adhesive layer; the claims do not

require that interpretation; alternative embodiments are explicitly claimed; and there is not legitimate basis to read such a definition into the claim language.

Thus, the Examiner's conclusion that the carrier sheet necessarily "defines" the hydrophobic adhesive layer is simply incorrect. Accordingly, adding a release layer over the exposed hydrophobic adhesive layer (e.g., claim 53) hardly departs from the originally presented inventive concept. A release liner is by definition a material that protects adhesive until contact is desired whereupon it is removed. Thus, placing a removable release liner over the claimed upper surface does not, as the Examiner suggests, preclude the adhesive layer from existing on or having an upper surface. No person of ordinary skill in the art would fail to appreciate that a release liner is removed prior to use. To assert otherwise to support a restriction requirement is non-sensical. Accordingly, Applicant requests withdrawal of the restriction requirement as it is not supported by practice under 35 USC 371 as the claims are directed to material having a common inventive aspect.

In paragraph 7, the Examiner restates that Nielsen teaches an adhesive layer in the form of a moldable backing. As articulated, moldable backing 14 is not a layer of adhesive and Nielsen explicitly teaches that that the upper surface as defined by this layer is non-tacky. Again, if the reference is taken to imply to the extent additional adhesive material is used to hold the moldable backing to the adhesive mass, this fails to teach the claims which require the adhesive on the upper surface so that as the wafer is rolled the lower surface (adhesive) contacts the upper surface (adhesive), which is quite distinct from the reference. Further, the mouldable backing does not equate to a release liner as it is not designed, configured, or intended to be removed while leaving an appropriate adhesive layer behind.

The Examiner also restates that Nielsen teaches locking the torus in the rolled configuration. Should the Examiner choose to maintain this line of argument, Applicant requests specific line citation to the reference where such locking is discussed. As noted, the Nielsen device is not adhered in the rolled position and is free to return to the original form (hence by definition not "locked") either with the aid of the person or – in direct contradiction to the Examiner's stated interpretation – by the "swelling" of the adhesive acting to unroll the torus (again, not "locked").

In summary, the present claims are directed to embodiments of an ostomy product having a wafer with two different adhesives disposed on opposite surface that are brought into contact with one another by rolling an edge and forming a torus. The interaction of these two adhesives (which are compatible with one another) serves to lock the torus into this configuration. Nielsen fails to teach providing an adhesive on the second or upper surface; fails to teach that a hydrophobic adhesive is used on the exposed upper surface; fails to teach engaging the first surface with the second surface; fails to teach engaging the first adhesive with second adhesive, and not only fails to teach locking the torus into this configuration through bonding of the adhesives but distinctly and explicitly teaches not locking the torus so that it unrolls to contact the stoma.

CONCLUSION

Applicant respectfully asserts that the pending claims are in condition for allowance and notice of the same is respectfully requested. Should any issues remain outstanding, the Examiner is respectfully urged to telephone the undersigned. No additional fee are believed due at this time; however, the office is authorized to charge any fees actually due and credit any overpayment to deposit account 50-4439.

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Respectfully submitted,
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